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September 25, 2008

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrisette Drive
Springfield, VA 22152

Dear DEA Federal Register Representative/ODL:

The Healthcare Information and Management Systems Society (HIMSS) is pleased to submit our comments regarding DEA's Proposed Rule "Electronic Prescriptions for Controlled Substances, Docket No. DEA-218 (DEA Reference Number: 21 CFR Parts 1300, 1304, et al. posted in June 27, 2008).

HIMSS is the healthcare industry's membership organization exclusively focused on providing leadership for the optimal use of healthcare information technology and management systems for the betterment of healthcare. HIMSS represents more than 21,000 individual, 375 corporate members, 31 healthcare providers, and 44 chapters nationwide. HIMSS seeks to shape healthcare public policy and industry practices through its educational, professional development, and advocacy initiatives designed to promote information and management systems' contribution to quality patient care.

As an organization, we are committed to supporting the development and distribution of information and management systems, across the healthcare continuum, to achieve greater patient safety, improved office efficiency, better quality of care, and cost effective care delivery. E-prescribing and the adoption of Electronic Health Records foster an environment where these improvements can be maximized.

HIMSS has previously responded to several federal requests for public comment on [e-prescribing](#), in particular, several public comment opportunities through the Centers for Medicare and Medicaid Services (CMS). To ensure that this response reflects the broadest level of industry experience, HIMSS has leveraged the subject matter expertise of the members of our Patient Safety & Quality Outcomes Committee, Ambulatory Information Systems Committee, Privacy & Security Committee, Financial Systems, Life Sciences Roundtable, Pharmacy Informatics Task Force, and the Electronic Health Record Association. The viewpoints of these groups, along with their industry colleagues, ensure that HIMSS fulfills its requirement to offer a coordinated voice to the national discussion on these important healthcare issues.

HIMSS appreciates the DEA effort to support and drive adoption of e-prescribing by issuing the new proposed rule, which outlines possible standards, to permit health care practitioners to write, and pharmacies to receive, dispense, and archive, electronic prescriptions for controlled substances is greatly appreciated.

HIMSS also appreciates the difficult balance of policy requirements DEA must address in developing a public policy on e-prescribing. We would be remiss, however, if we did not highlight the benefits e-prescribing brings to the health care system, including the potential reduction of medication errors caused by illegible handwriting and misunderstood oral prescriptions. E-prescribing increases documentation and clinical care efficiencies by accurately and immediately integrating prescription data with other medical records and improving patient care, safety, and outcomes by making patient compliance with prescription recommendations fully visible to clinicians. DEA notes that the government supports electronic prescriptions for controlled substances for such reasons.

Our recommendations are based on feedback from the ambulatory provider and pharmacy perspectives. Pragmatically addressing issues of clinical workflow for prescribers (physicians, physician assistants, nurse practitioners, pharmacists) is of vital importance to the success of DEA's efforts in promulgating a regulation that will be embraced by prescribers and simultaneously weave in the necessary legal safeguards for the e-prescribing of controlled substances.

We would like DEA to be aware that pharmacists play an important role in all aspects of the prescribing process: as consultants providing drug information and recommendations to providers in the outpatient and inpatient environments prior to prescribing, as providers generating prescriptions under collaborative practice agreements according to each individual state's legislation (e.g., Montana), and as recipients of prescriptions presented by patients or healthcare providers for dispensing. The proposed rule impacts the pharmacist "provider" and "dispensing" role the most.

Pharmacists are excluded from consideration as providers with prescriptive authority in the proposed regulation. If the proposed regulation is adopted, pharmacists currently practicing under a collaborative practice agreement may find their professional scope significantly altered, i.e., patient care may need to be redirected in some cases. The regulation will become a barrier to the further involvement of pharmacists as part of the interdisciplinary healthcare team, especially for pharmacists that seek prescriptive authority under collaborative practice agreements.

Unfortunately, DEA recommendations accommodate workflows present in the inpatient environment more than the outpatient/ambulatory practice of medicine. Today, the vast majority of prescription activity is actually related to patients with chronic illnesses who are treated at, or near, the patient's home. This is an out-patient setting that has little or any contact with inpatient workflow and systems other than during emergencies. A summary of our comments are as follows:

89 • **1311.105 - In-person identity proofing and 1311.110 - Two-factor Level 4**
90 **authentication**

91 This requires that an electronic prescribing system only be accessible with a hard
92 token, uniquely coded for each practitioner, who will electronically prescribe
93 controlled substances. A number of devices could serve this purpose, including
94 PDAs, Blackberries, external storage devices, and multi-factor, one-time-use,
95 password tokens.

- 96 ○ We recommend DEA consider allowing the option of hard-token *or*
97 biometric authentication. Hard-token authentication for the ambulatory
98 prescriber has cost, technology and workflow implications. As one
99 example, there is no provision for on-call situations when a token might
100 not be available to use to prescribe.
- 101 ○ We would like to make DEA aware of some potential strategies, both
102 testimonies provided on behalf of the American Health Information
103 Community (AHIC):
 - 104 ▪ [Current national practice of the Association of American Medical](#)
105 [Colleges \(AMMC\) of using a fingerprint biometric strategy to](#)
106 [permanently identity proof all future physicians at the time they](#)
107 [take their entrance exam](#)
 - 108 ▪ [Various aspects of identity proofing, confidentiality, and security,](#)
109 [including professionals and patients](#)
- 110 ○ *Other Registrant Requirements: Summary* – (1) A Registrant must have
111 separate passwords/keys for each of its DEA registrants and may only use
112 one of its DEA registrants for any prescription. (2) A Registrant must
113 retain sole possession of the hard token and must notify the service
114 provider within 12 hours of discovery that the hard token is lost or
115 compromised. (3) Failure to so notify the service provider will result in the
116 Registrant being held responsible for any prescriptions written with that
117 token. This is too restrictive and burdensome both in the short time frame
118 (12 hours) and the physical requirement of minding the token.
- 119 ○ Whether the pharmacy, the pharmacy information system, the prescriber
120 or the patient pays, there are costs associated with the technology,
121 software development and oversight. If the Notice of Proposed Rule
122 Making (NPRM) outlines the ‘minimum’ oversight, then while it is an
123 option (pre-2012), prescribers will likely still print or hand-write
124 controlled substances prescriptions. This would be a very undesirable
125 adverse consequence of the proposed rule because it would seriously delay
126 the precise patient care, safety, and efficiency improvements that e-
127 prescribing is designed to accomplish in the first place.

128
129
130 • **1311.105 - Check validity of State license and DEA registration. 1311.165 -**
131 **Check the validity of the prescriber's DEA registration (Pharmacy)**

132 The pharmacy system must check a prescribing practitioner's DEA registration to
133 verify that it is valid or have an intermediary system do so. This is a time
134 consuming step and extra work requested from the pharmacies.

- The proposed rule, which requires the pharmacy ensure that the prescriber's DEA registration number was valid at the time the prescription was electronically signed, is more stringent than the rule currently applied to paper prescriptions where the pharmacist bears the responsibility of ensuring the prescriber's DEA registration is current. Incorporating a check into every prescription will entail additional pharmacy expense for database subscriptions and/or interface work to enable the pharmacy system to perform this check. Some chain pharmacies have this function already, while other pharmacies perform a check against a database that is updated on a periodic basis (monthly or quarterly). This requirement places the greatest burden on independent pharmacies.
- We recommend DEA apply to electronic prescriptions the same standards that are in place for verifying the validity of a prescriber's DEA number for paper prescriptions.

- **1311.125 - Limit access to signing function.**

The system must limit signing authority to those practitioners that have a legal right to sign prescriptions for controlled substances. Accordingly, the system must have varying levels of access based upon responsibility. The practitioner must authenticate to the system immediately before signing an electronic prescription. Prior to transmitting that prescription, the system must present a statement that the practitioner understands he is signing the prescription.

If the practitioner does not then perform the signature function, the prescription cannot be transmitted. In practices where a prescriber uses an EMR, DEA's recommendations are counterproductive to clinical workflow requiring extra authentication at the point of transmission. This requirement segregates controlled substance prescriptions from non-controlled substance prescriptions, disrupting workflow. Batch approvals of controlled substance prescriptions prepared by a surrogate or scribe without being in each patient's chart, lends itself to issues of patient safety. For example, batch approval of multiple controlled substance prescriptions for multiple different patients is a patient safety risk. For instance, in an EMR, if the 'task' list shows normal and abnormal lab results for 25 different patients in a list, it is 'safe' to approve all 25 in a batch as they are all 'normal'. However, if there was a list of 25 patients with 'written' but not 'transmitted' prescriptions for controlled substances it would be unsafe and unwise to batch approve all of those prescriptions for controlled substances. These interruptions to workflow in the use of an EMR will require ambulatory EMR vendors to consider redevelopment of their software to accommodate redesign:

- a. At the screen level
- b. At the user permissions level (surrogate can 'write' but not 'transmit' controlled substances)

c. Require an additional cost beyond today's version of e-prescribing in ambulatory EMRs that will impact providers financially.

- Recognize that there are a large number of multi-state prescription situations (as examples, Colorado, Utah, New Mexico, or DC, Maryland, and Virginia). Therefore, to implement the proposed rule, there will be a need for multi-state registrations to be maintained in the e-prescribing system. Within the EMR, this will likely require software development of new systems that checks the home address of the patient and decide which identifier to transmit.

- **1311.130 - Transmit as soon as signed and 1311.130 - Do not transmit if printed; do not print if transmitted.**

The system must transmit the prescription immediately upon it being signed and the system must not allow printing of prescriptions that have been transmitted. Conversely, if a prescription is printed from the system, the system must not allow it to be subsequently transmitted. The system must not permit the alteration of a prescription, other than by reformatting, during transmission. The prescription may not be converted to other transmission methods (e.g., facsimile) during transmission.

HIMSS is concerned that this is not a realistic expectation as hurricanes, earthquakes, fires, and other disruptions prevent patients from filling their prescription at the initially-designated pharmacy, provider and pharmacy information systems have failures and downtime, and many kinds of data transmission errors can occur. Serious patient harm may be inadvertently caused by DEA's specification of a system that is too stringent to cope with the everyday challenges that exist in healthcare.

The prescriptive process is dynamic and fluid. Though it is generally interwoven through accepted workflows, there is considerable breadth of flexibility to accommodate the endless variety of life's situations that clinical care requires. One not uncommon situation is the need to reprint or resend a prescription to the pharmacy; the reasons are legion and the provided list only begins to scratch the surface of reasons why a prescription should be reprinted or resent.

- A copy is needed for the insurance company
- A copy is needed for a pharmacy audit
- A copy is needed for the chart – many charts are still mixed (hybrid of paper and electronic media). Even if a copy of the prescription is printed, it can be scanned in the EMR, for additional documentation.
- A copy is needed for nursing services
- A copy is needed for patient or caregiver records
- A copy is needed to satisfy the requirements of a patient contract
- A copy is needed due to a technical failure in the fax, computer, network access, or internet

- A copy is needed to perform clinical work at a remote site where computer access is not possible; the prescription is needed as a reference.

Not all these situations require a prescription in the sense of a legal instrument for dispensing. Rather, the majority of situations require the prescription information. Regulatory tools are currently in place to satisfy security concerns while allowing the flexibility required ensuring patient care is not adversely affected. The NPRM does not preserve this flexibility.

- We recommend DEA to allow a prescription to be sent and/or printed with an identifier “The original, legal version of this prescription was sent to XXXX on (MM/DD/YYYY) at (xx:yy AM/PM EDT). THIS copy is solely for informational purposes, and may not be accepted for dispensing or equivalent at any time during the prescriptive process.”
- In the event the prescription is needed as a legal instrument (such as a technical malfunction), we recommend DEA to allow documentation or annotation to the prescription explaining the purpose of the resend, and include such action as an auditable event (for pharmacy records) or on the prescriber’s log for monthly review.
- We recommend that DEA consider allowing a void or recall process when transmission fails (allow print), or when print fails (allow transmit).
- We recommend that DEA require the full support of all transaction types of the approved CMS standard including fill status notification (RXFILL), cancel prescription notification (CANRX) transactions, and prescription change transactions (RXCHG), throughout the prescribing process for controlled substances. Using these transactions supports medication adherence monitoring and decreases opportunities for diversion. These transactions are already present in the NCPDP SCRIPT standard. These transactions also perform a valuable role in medication therapy management (MTM) programs required by the Medicare Modernization Act of 2003.
- Consider allowing alteration of prescription elements by the pharmacist as provided in state laws. Pg 36744 of the NPRM states, “If, however, there are cases where the content of the required elements is altered (e.g., to change the prescribed drug to a generic drug) after signing, DEA would consider the prescription invalid [...]” which is in direct conflict with many state laws.
 - For example: New York State Law (Article 137, Education Law, Pharmacy, Section 6816-a). A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met: (a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber does not prohibit substitution, or in the case of oral prescriptions, the prescriber must expressly state whether substitution is to be permitted or prohibited. Any oral prescription that does not include such an express statement shall not be filled; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and
(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

From Title 10 CFR, Part 80 - Controlled Substance Regulations 80.73

(m) When an official New York State prescription prepared by a practitioner is incomplete, **the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription.** The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(n) **A practitioner may orally authorize a pharmacist to change information** on an official New York State prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

- **1311.140 - Generate monthly logs for practitioner review**

The system must generate and send each practitioner a monthly log of all electronic prescriptions for review. Each practitioner must affirmatively indicate that he reviewed the log and must maintain the log for five years.

- Recognize that this is an unrealistic expectation on a provider's time. This rule could place a tremendous and infeasible new workload on each provider. Practitioners who solely work in a single hospital and solely support in-patient care might be fortunate to receive a single monthly

report. The vast majority of other clinicians will instead receive reports from dozens and dozens of disparate in- and out-of-state pharmacies each month. Not only is such an erratic avalanche of monthly reports unmanageable, it may make it almost impossible for any clinician to effectively or reliably pick out the one or two patients who have intentionally abused the intended e-prescribing system safeguards. Another perspective for consideration is that a single provider may submit prescriptions to potentially 50 pharmacies, which are actively used by his patient base. Each system would be required to produce a log (50 logs), and each log would require physician review.

Verifying in-person prescribers, keeping monthly logs and indication of prescriber 'review' will probably add costs to the point-of-care vendors, pharmacy vendors, prescribers and pharmacists. In addition, costs for pharmacies and pharmacy system vendors will likely increase which will affect third parties (e.g., commercial pharmacy chain, patient, payer, other). As well, this is not a traditional role for a service provider (vendor), and identity credential management should be performed by a traditional certificate authority vendor, if ultimately required.

- **1311.160 - First recipient (or last transmitter) digitally signs the prescription as received**

These rules assume the pharmacy system has the capability of digitally signing prescriptions. Adding this functionality will result in additional expense for the pharmacy. Many pharmacy software systems do not have this functionality built in and it will need to be developed.

- We recommend DEA include the projected expense of adding this technology to existing pharmacy systems in their proposal.

- **1311.150; .170 - SysTrust, WebTrust, or SAS 70 audit.**

The pharmacy system must create an audit trail that identifies each person who annotates or alters an electronic prescription record, and must conduct daily internal audits. The pharmacy system also must undergo a third-party audit meeting the requirements of SysTrust or SAS 70 audits for security and processing integrity. Realize that this requirement is a burden, both financially and logistically. The requirement to perform an expensive annual security audit on the part of the vendors will increase the cost to pharmacies as the extra charge is passed on to the vendor's customers. The preamble to the proposed rules cited the cost of an electronic prescribing transaction, however; the additional cost levied by the pharmacy system vendor for processing electronic prescriptions was not given or acknowledged. These additional charges to the pharmacy may be significant and result in a detrimental effect on adoption of e-prescribing adoption, especially by independent pharmacies. The current economic analysis compared the expected cost attributable to this requirement against pharmacy

sales. Since the cost of drugs is exceedingly high, a better estimation of the impact of this cost is on net revenue.

Be aware, that in safety-net clinics, where the clinic is also a licensed user of a pharmacy information system and employs pharmacists and pharmacy technicians to prescribe medications for uninsured patients (there is no Pharmacy Benefit Manager (PBM) or plan), this proposal will greatly increase costs. Where an ambulatory private physician office is only paying the prescriber side of this new technology (not inexpensive), the safety-net clinic must pay the prescriber requirements and the service provider requirements (pharmacy information system vendor) plus assume the expense of all the registration verification and daily audit logs.

- We recommend DEA evaluate the potential economic impact of this requirement against a pharmacy's average net revenue as opposed to a percentage of total sales, which results in an underestimate. As an example, the NPRM cites \$0.215 as the fee charged by SureScripts, yet the invoice for the pharmacy reflects a SureScripts charge of \$0.30 per prescription. A pharmacy can easily process 2,000 prescriptions a week. Even if half the prescriptions are billable electronically, this represents an additional \$300 actual weekly expense, equivalent to a full FTE at higher-than-minimum wage.

- **1311.170 - Have a back-up system for records at another location (Pharmacy)**

This rule may adversely affect independent and small chain pharmacies as they incur the significant expense and logistics of maintaining a remote data storage site with appropriate security is significant. From a patient safety perspective, electronic prescription information is captured in many other systems and can be reconstituted in the event of a disaster or emergency. These systems may include e-prescribing networks, intermediaries, insurers, the prescriber's e-prescribing application, and electronic personal health records.

As with many specific solutions contained within DEA proposed rule, HIMSS believes that *risk* to privacy, security (including the elements of confidentiality, integrity and availability) should be the focus of DEA rule, not a singular specific solution. In this case, the risk is a regional disaster, how to handle business continuity in this type of environment has well established best-practices. These best-practices are also focused regionally to the likely disasters.

From a patient safety perspective, electronic prescription information is captured in many other systems and can be reconstituted in the event of a disaster or emergency. These systems may include e-prescribing networks, intermediaries, insurers, the prescriber's e-prescribing application, and electronic personal health records. The availability of copies of the data in other systems should be factored into the risk analysis.

402 ○ We recommend DEA remove the specification of “geographically separate”
403 from the rule and focus instead on requiring the organization to perform back-
404 up appropriate to their own risk determination in this area.

405 • **1311.170 - Have an internal audit trail and analyze for auditable events**
406 **(Pharmacy)**

407 These rules assume the pharmacy system has the capability of capturing and reporting
408 on auditable events. Adding this functionality will result in additional expense for the
409 pharmacy, affecting primarily independent pharmacies. Further, standards for the
410 automation of capturing auditable events and interpretation of the resulting reports
411 have not been published. Many pharmacy systems have the ability to track auditable
412 events, but not all have the ability to generate the reports desired by DEA.

413 ○ We recommend DEA provide clarification regarding the expectations
414 associated with the internal audit process.

415 • **Additional Comments: Long-term Care**

416 The adoption of e-prescribing is considered vital to reducing medication errors and
417 improving quality of care across the health care spectrum, including long-term care.
418 For the nation’s nearly 2 million seniors who receive care in nursing facilities, e-
419 prescribing promises not only to improve quality but also to improve efficiencies.
420 Yet, long-term care facilities are at risk of being left behind as the rest of the health
421 care system moves toward adoption of electronic prescribing and electronic health
422 records. This is because, despite a recommendation from the pilot study of e-
423 prescribing in long-term care facilities¹ and from the National Committee on Vital
424 and Health Statistics (NCVHS)², the Department of Health and Human Services
425 (DHHS) continues to exempt long-term care facilities from using the voluntary
426 standards for e-prescribing established as part of the Medicare Prescription Drug,
427 Improvement and Modernization Act of 2003 (MMA).

428
429 DEA’s proposed rules for e-prescribing of controlled substances continues this
430 pattern by not including the unique requirements found in the long-term care
431 prescribing process. The prescribing process in long-term care involves three entities:
432 the prescriber, the nursing facility and the pharmacy. Although federal regulations
433 mandate that each resident’s medical care be supervised by a physician, 42 CFR
434 483.40(a)(1), physicians typically are not on site 24/7 in long-term care facilities.

¹ According to the report of the pilot study on e-prescribing, “The study found some areas in which the [MMA] e-Prescribing standards did not meet the needs of LTC, and minor revisions were not possible during the pilot. . . . In order to continue the successful adoption of e-Prescribing in LTC, it will be critical for new/revised standards to be developed that will address these problematic issues. CMS needs to include the LTC environment in the NCPDP Medicare Part D initiative to drive adoption in this market.” [Long Term Care e-prescribing Standards Pilot Study.](#)

² [Letter to Michael O. Leavitt](#) from Simon P. Cohn, M.D., M.P.H., Chairman, National Committee on Vital and Health Statistics, May 22, 2008 “NCVHS also recommends lifting the current exemption from the requirement to use the NCPDP SCRIPT standard for non-prescribing providers in long-term care settings. . . . While long-term care facilities would be able to voluntarily use the NCPDP SCRIPT 10.5 standard even while the exemption is in place, we believe lifting the exemption sends a clear message to the industry about the desirability of e-prescribing in long-term care.”)

Thus, nurses play a vital role in communicating information to physicians, recording their verbal orders in the resident's clinical record, conveying prescription orders (often by fax) to the pharmacy and ensuring that medications are administered on time. As a matter of practice, the long-term care facility nurse acts as the agent of the prescriber in the same manner that a nurse in a hospital acts as an agent of the prescriber. Recognizing that the long-term care facility nurse plays a key role in the prescribing process in long-term care facilities, the CMS Long-Term Care E-Prescribing Standards Pilot Study treated the nurse as the agent of the prescriber. In the pilot, 94% of the orders at both test sites were entered by long-term care nurses as agents of the prescriber. Nurses were also responsible for transmitting the e-prescription to the pharmacy.

In a 2001 Federal Register notice, DEA stated that a nurse in a long term care facility cannot be the agent of the prescriber because there is no direct employment relationship between the prescriber and the nurse.³ DEA's proposed e-prescribing rule for controlled substances fails to account for the unique prescribing process that exists in long-term care.⁴ There is no mention or allowance for transmitting a prescription for a controlled substance from a facility to the pharmacy (allowing for prescriber review and sign through a secure interface) or for allowing a prescriber to transmit a prescription for a long term resident directly to the pharmacy with a parallel message to the facility so that the resident's medical record can be updated. In fact, the proposed rule explicitly prohibits such dual transmission.

Unless DEA provides a clear process to enable a three party transaction, long-term care facilities and the residents they serve will continue to be left behind as the nation's healthcare system moves to adopt e-prescribing as the standard of practice. It bears repeating that "[w]ithout LTC, a significant part of the continuum of care is missing. As the LTC industry continues to grow in the coming years, the opportunity cost of not addressing LTC e-prescribing may become dramatic."⁴

- We recommend DEA specifically recognize the long-term care facility nurse as an agent of the prescriber.
- We recommend DEA allow a prescription to be sent and/or printed with an identifier "For informational purposes, not for dispensing" or equivalent at any time during the prescriptive process.

Conclusion:

The benefits to patients and society from the e-prescribing will be enormous, and HIMSS greatly appreciates and commends DEA's efforts to ensure that controlled substances are adequately protected in any new systems. HIMSS hopes that through the above comments, it is clear that we are strongly recommending to DEA that the final ruling very carefully and explicitly avoids adding significant new expenses, physician labor, and workflow impediments that could inadvertently -- but powerfully -- defeat or delay the overall intended benefits of e-prescribing in the full range of in- and out-patient settings

³ 66 Fed. Reg. 20834 (April 25, 2001).

⁴ See American Society of Consultant Pharmacists – LTC Prescribing Process, Long Term Care e-Prescribing Standards [Pilot Study](#).

477 used to support patients with acute and chronic illnesses. HIMSS does not think that any
478 such defeat or deferral of e-prescribing systems would ultimately be in the DEA's or the
479 public's interest. Such a system would not only put DEA in the unenviable position of
480 relying on two disparate systems -- new, computerized systems and antiquated manual
481 paper prescription systems -- until 2012 or later (and will likely delay industry-wide
482 adoption of e-prescribing-compatible systems until close to 2012).

483
484 In making its decisions about the final rule, HIMSS strongly recommends that DEA
485 carefully consider that even if it eliminates and corrects the problematic items that we
486 have identified above, DEA will still gain huge new advantages from new e-prescribing
487 systems. DEA will finally be able to harvest timely and accurate electronic data sets
488 from providers and dispensers, which will give it very important access to new analytic
489 tools and reports to guide its own activities and future rulings. HIMSS therefore does not
490 think it is in DEA's or public interest to be overly aggressive in this current ruling, and
491 respectfully requests that DEA implement all of the above suggested revisions. They do,
492 indeed, represent the collective 'best counsel' of hundreds of our members and advisers,
493 who engage in the delivery of medical care each and every day.

494
495 HIMSS and our members commend DEA for its proactive stance on e-prescribing of
496 controlled substances. We are encouraged by the recent activity on Capitol Hill and thank
497 the DEA for engaging with HHS agencies and the Centers for Medicare & Medicaid
498 Services. HIMSS look forward to working with the federal government to develop
499 procedures that capitalize on HIT and the subsequent improvements in supply tracking
500 and drug dispensing patterns that e-prescribing enables for controlled substances. HIMSS
501 appreciates CMS's efforts on e-prescribing and expanding the use of effective
502 technologies.

503
504 If you have any additional questions please contact [David A. Collins](#), Director,
505 Healthcare Information Systems, 703.562.8817 or [Thomas M. Leary](#), Senior Director,
506 Federal Affairs, 703.562.8814. Thank you for consideration of these comments which
507 represent the input from membership.

508
509 Sincerely,

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512
513 H. Stephen Lieber, CAE
514 HIMSS President/CEO

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